

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION)	MDL No. 2804
OPIATE LITIGATION)	
)	Case No. 17-md-2804
THIS DOCUMENT RELATES TO:)	
)	Judge Dan Aaron Polster
ALL CASES)	
)	<u>OPINION AND ORDER</u>
)	

In this Multidistrict Litigation (“MDL”), public entities from across the nation have sued manufacturers, distributors and retailers of prescription opiate drugs, alleging they are liable for the costs Plaintiffs have incurred, and will continue to incur, in addressing the opioid public health crisis. To assist the Court and parties in litigating (and hopefully settling) these cases and beginning to abate the crisis, the Court directed the Drug Enforcement Agency (“DEA”) and the Department of Justice (“DOJ”) (collectively, the “United States”) to produce transactional data for all 50 States and several Territories from its Automation of Reports and Consolidated Orders System (“ARCOS”) database.¹ Because the data contains law enforcement-sensitive information and confidential commercial information of the reporting manufacturers, distributors and retailers, the DEA does not release ARCOS data publicly. The DEA has produced the ARCOS data to certain entities and individuals in this MDL at the direction of the Court for this litigation

¹The United States is not a party in this MDL but has filed an appearance as a friend of the Court. Doc #: 212; 6/19/2018 non-document order.

only, Doc #: 233, 397, 400, and under the safeguards of a Protective Order, Doc #: 167 – an Order that was rigorously negotiated over a significant period of time by the parties in the MDL and the United States.² Further, the United States agreed to the disclosure of ARCOS data to State Attorneys General (“State AGs”) “specifically conditioned upon” the DEA and DOJ receiving a list of the State AGs who receive the data, a copy of the Protective Order Acknowledgment Form signed by each State AG who receives the data, notice of any distribution of the data by any State AG to any other authorized individuals, and notice of, and the opportunity to object to, any public records request submitted to any State AG for the data. Doc #: 542 at 1.

Certain recipients of the ARCOS data – Cuyahoga County, Ohio, Summit County, Ohio, and Cabell County, West Virginia (hereafter, “the Counties”) – have received public records requests from the Washington Post and HD Media (together, “the Media”) asking for copies of the ARCOS data furnished to the Counties in the course of discovery in this MDL. The Court has reviewed the briefs of the entities favoring disclosure of the ARCOS data to the Media. Doc #: 718 (Washington Post); Doc #: 719 (Track One Plaintiffs), Doc #: 725 (HD Media). The Court has also reviewed the briefs of entities objecting to disclosure of this data to the Media. Doc #: 603, 717³ (DEA/DOJ); Doc #: 605 (Distributor Defendants); Doc #: 621 (Manufacturing

²See, e.g., Doc #: 112 at 2 (“There is a legitimate need for Plaintiffs to obtain this data, but the Court believes that production must be tailored – perhaps through a protective order – in a way to address the DEA’s concerns regarding breadth, years in question, potential interference in investigations and enforcement actions, and divulging the location of warehouses where opioids are stored.”); Doc #: 233 at 22 (“Use of the ARCOS database shall be limited to this litigation and for State and local law enforcement purposes only. No person shall disclose the data or allow use of the data except as necessary for a submission to the court or at trial.”); Doc #: 397 at 3, Second Order Re: ARCOS Data (expanding dissemination of ARCOS data to all States and Territories “for State and local law enforcement purposes only.”)

³Following the United State’s filing of a heavily redacted Brief in Support of Objections, Doc #: 663, the Washington Post filed a Motion for Access to the United States’ (Unredacted)

Defendants), Doc #: 665 (Chain Pharmacy, Manufacturing and Distributor Defendants). The Court is now prepared to issue a ruling.

I. Standard of Review

In 1983, the U.S. Supreme Court expressly recognized a First Amendment and common law right to inspect and copy judicial records and documents. *Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597 (1978). *Nixon* preceded a long line of Supreme Court decisions affirming the principle of open access to criminal trial and pretrial proceedings and documents. Even the *Nixon* Court recognized, however, that the First Amendment right of access to criminal proceedings and documents is not absolute. *Id.* at 598. “Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes.” *Id.*; see also *Associated Press v. United States District Court*, 705 F.2d 1143, 1145 (9th Cir. 1983) (prohibiting, e.g., access to grand jury proceeding transcripts and/or anything conflicting with a criminal defendant’s Sixth Amendment right to a fair trial).

Later that year, the Sixth Circuit applied the presumptive right of access to proceedings and documents in criminal cases, articulated in *Nixon*, to sealed judicial documents in civil cases. *In re Knoxville News-Sentinel Co., Inc.*, 723 F.2d 470, 474-45 (1983); *Brown & Williamson Tobacco Corp. v. FTC*, 710 F.2d 1165, 1178 (1983). The Sixth Circuit acknowledged, however, that this right is not absolute. Specifically, “trial courts have always been afforded the power to

Brief in Support of Objections, Doc #: 662. Doc #: 672. This prompted the United States to file an Amended Brief in Support of Objections, Doc #: 717, that removed all but necessary redactions, the Court having reviewed and compared the unredacted and final briefs and having so concluded. Accordingly, the Motion for Access, **Doc #: 672**, is **denied as moot**.

seal their records when the interests of privacy outweigh the public's right to know." *Brown & Williamson*, 710 F.2d at 1179, *Knoxville News-Sentinel*, 723 F.2d at 474. "[T]he decision as to when judicial records should be sealed is left to the sound discretion of the district court, subject to appellate review for abuse." *Knoxville News-Sentinel*, 723 F.2d at 474.

None of these standards of review apply to protective orders issued in the course of discovery in civil cases.⁴ Several Federal Rules of Civil Procedure are devoted to this discrete aspect of civil litigation. Rule 26(b)(1) addresses the expansive scope of discovery. It provides:

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within the scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. 26(b)(1).⁵ Due to the expansive nature of discovery, Rule 26(c)(1) provides that "a court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" arising from a discovery request. The Rule further provides that a protective order may, among other things, forbid requested discovery or disclosure, specify the terms for discovery or disclosure, forbid inquiry into certain matters or limit the scope of discovery or disclosure to certain matters, or require that trade secret or commercial information not be revealed or that it be revealed only in a specified way.

⁴*See, e.g., Howes v. Ashland Oil, Inc.*, No. 87-5939, 932 F.2d 968 (table), 1991 WL 73251, at *7 (6th Cir. May 6, 1991) ("Private documents collected during discovery are not judicial records . . .")

⁵*See also Lewis v. ACB Bus. Serv., Inc.*, 135 F.3d 389, 402 (6th Cir. 1998) ("[T]he scope of discovery under the Federal Rules of Civil Procedure is traditionally quite broad.").

See Rule 26(c)(1)(A)-(H).

“Protective orders issued under Rule 26(c) serve the vital function of securing the just, speedy, and inexpensive determination of civil disputes by encouraging full disclosure of all evidence that might conceivably be relevant,” an objective which “represents the cornerstone of our administration of civil justice.” *SEC v. TheStreet Com*, 273 F.3d 222, 229 (2d Cir. 2001) (internal quotation marks, alterations, and citations omitted); see also *In re Zyprexa Injunction*, 474 F.Supp.2d 385, 413 (E.D. N.Y. 2007) (“As civil discovery rules became more expansive over the course of the last century, the role of the courts in protecting producing parties from undue invasions of privacy has correspondingly increased.”).

Flagg ex rel. Bond v. City of Detroit, 268 F.R.D. 279, 291 (E.D. Mich. 2010). “Because of the liberality of pretrial discovery permitted by Rule 26(b)(1), ‘it is necessary for the trial court to have the authority to issue protective orders conferred by Rule 26(c),’ in order to regulate the use and disclosure of information that ‘if publicly released could be damaging to reputation and privacy.’” *Id.* at 292 (quoting *Seattle Times Co. v. Rinehart*, 467 U.S. 20, 32 (1984)); *U.S. v. Aguilar*, 515 U.S. 593, 606 (1995) (“[P]rotective orders may be imposed in connection with information acquired through civil discovery without violating the First Amendment.”); *In re Carpenter Co.*, No. 14-0302, 2014 WL 12809636, at *1 (6th Cir. Sep. 29, 2014) (“The district court exercises great discretion over pretrial discovery, which typically occurs outside the public eye.”).

The *Seattle Times* Court explained that “an order prohibiting dissemination of discovered information before trial is not the kind of classic prior restraint that requires exacting First Amendment scrutiny.” *Id.* at 33 (quoting *Gannett Co. v. DePasquale*, 443 U.S. 368, 399 (1979)). “[S]uch a protective order prevents a party from disseminating only that information obtained through use of the discovery process.” *Id.* Additionally, discovery such as “pretrial depositions and interrogatories are not public components of a civil trial. Such proceedings were

not open to the public at common law, . . . and, in general, they are conducted in private as a matter of modern practice.” *Seattle Times*, 467 U.S. at 33 (quoting *Gannett*, 443 U.S. at 99). Thus, “restraints placed on discovered, but not yet admitted, information are not a restriction on a traditionally public source of information.” *Id.* at 33. In the wake of *Seattle Times*, federal courts have uniformly recognized the more lenient standard governing the restriction of discovery in civil cases. *See, e.g., U.S. v. Anderson*, 799 F.2d 1438, 1441 (11th Cir. 1986); *Marshall v. Bramer*, 828 F.2d 355, 360 (6th Cir. 1987); *Chicago Tribune Co. v. Bridgestone/Firestone, Inc.*, 263 F.3d 1304, 1310-11 (11th Cir. 2001); *Citizens First Nat’l Bank v. Cincinnati Ins. Co.*, 178 F.3d 943, 944 (7th Cir. 1999); *Baxter Int’l, Inc. v. Abbott Labs.*, 297 F.3d 544, 545 (7th Cir. 2002). Moreover, courts have approved protective orders in cases involving matters of great public interest. *See, e.g., Seattle Times*, 467 U.S. at 31 (upholding prohibition on public dissemination of discovery even where “there certainly is a public interest in knowing about respondents.”); *The Courier Journal v. Marshall*, 828 F.2d 361, 364 (6th Cir. 1987) (upholding a protective order even where the proceedings were “of intense public concern.”).

HD Media, which basically challenges the Court’s Protective Order via public records requests to the Counties, argues that the ARCOS data “is stale historic information.” Doc #: 725 at 1. HD Media further argues that none of the ARCOS data sought “is entitled to protection under trade secret, privacy or law enforcement exemptions” of the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552(b)(4) (or the state FOIA analog, for that matter) under Federal Rule of Civil Procedure 26(c). Doc #: 725 at 1. In support, HD Media cites *State of West Virginia ex rel. Patrick Morrissey v. AmerisourceBergen Corp., et al*, Civil Action No. 12-C-141, and *State*

of *West Virginia ex rel. Patrick Morrissey v. Cardinal Health*, Civil Action No. 12-C-140 (together, the “West Virginia cases”).⁶ Respectively, Doc #: 725-1, 725-2. Specifically, HD Media contends that detailed West Virginia ARCOS data for 2007-2012 “is currently in the public domain and none of the harm claimed here occurred as a result of its disclosure in 2016.” *Id.*

There are numerous legal and factual distinctions between the West Virginia cases and this MDL. First, as previously noted, a protective order prevents a party from disseminating only that information obtained through use of the discovery process. “Thus, the party may disseminate the identical information covered by the protective order *as long as the information is gained through means independent of the court’s processes.*” *Seattle Times*, 467 U.S. at 34 (emphasis added). Second, the decision of the West Virginia court on how to supervise its civil cases does not have any precedential effect on how the undersigned supervises discovery in this MDL. Third, in the West Virginia cases, the Charleston Gazette-Mail asked the court to unseal second amended complaints; here, the Media is asking the Counties to disclose the federal government’s entire ARCOS dataset produced within the confines of a protective order in the course of discovery in this MDL. As shown above, the standard of review for challenging a protective order during discovery (a showing of good cause) is much more lenient than the standard of review for unsealing judicial documents (a presumption of public access). Finally, the reason cited by defendants in the West Virginia cases as a basis for denying the motion was confidential commercial injury. Here, the United States cites as a basis for nondisclosure, in

⁶The Washington Post devotes much of its brief to the same arguments, prominently citing as support the West Virginia case against AmerisourceBergen Drug Corporation, *Brown & Williamson* and *Knoxville News-Sentinel*. See Doc #: 718 at 3-9.

addition to confidential commercial information, the need to protect law enforcement-sensitive information, which is a subject this Court takes very seriously.⁷

In sum, a showing of “good cause” under Rule 26(c)(1) is sufficient to meet constitutional and common-law objections to a protective order that restricts the disclosure of certain discovery to unauthorized users, whether these materials are filed with the court in connection with discovery matters or remain solely in the possession of the parties and their counsel. *Flagg*, 268 F.R.D. at 294 (citing *Chicago Tribune*, 263 F.3d at 1310-11.). For the following reasons, the Court – taking into consideration the arguments set forth in the briefs filed by the Media, Track One Plaintiffs, the United States and the Defendants – finds that good cause does in fact exist for the Protective Order’s prohibition against disclosure of ARCOS data to the Media.

II. Analysis

Controlled substances are drugs that are regulated by state and federal laws that aim to control their unlawful dissemination due to the dangers of addiction, physical and mental injury, and abuse. The Controlled Substances Act, Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (“CSA”), is the statutory scheme of the federal government under which the manufacture, distribution and use of certain narcotics is regulated (or “controlled”). The DEA is authorized to enforce the CSA, 21 U.S.C. §§ 801, *et seq.*, by

⁷HD Media also cites as a basis for disclosure of the ARCOS data to the Media in this MDL, the 2016 decision of the West Virginia Board of Pharmacy to release to HD Media 7000 suspicious order reports filed by drug distributors from 2012 to 2016. Doc #: 725 at 2. A decision by a state pharmacy board to release some of the ARCOS data under certain circumstances has no bearing on whether this Court should release the entire ARCOS dataset to the Media – data that has been produced to the parties and the State AGs pursuant to the carefully crafted Protective Order in this MDL.

investigating unlawful trafficking in controlled substances and cooperating with counterpart agencies that are investigating illicit trafficking of controlled substances.

Controlled substances are divided into five schedules. Prescription opiates such as oxycodone, oxymorphone, hydromorphone and fentanyl are controlled substances that may only be dispensed pursuant to a doctor's prescription. They have been upgraded from Schedule III controlled substances (which have the potential for abuse that may lead to moderate or low physical dependence or high psychological dependence) to Schedule II controlled substances (which have a high potential for abuse that may lead to severe psychological or physical dependence). 21 U.S.C. §§ 812 (b)(2), (b)(3).

ARCOS is a creature of federal law, maintained by the DEA in accordance with 21 U.S.C. §§ 827, 831, 958; 5 U.S.C. §§ 552 and 552a; 21 C.F.R. §§ 1304. It is "an automated comprehensive drug reporting system which monitors the flow" of certain controlled substances, including opioids, "from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level" so that "[f]ederal and state government agencies" can "identify the diversion of controlled substances into illicit channels of distribution." *ARCOS: Background*, DEA DIVERSION CONTROL DIVISION, available at <https://www.deadiversion.usdoj.gov/arcos/> (last visited on July 26, 2018). To effectuate that purpose, federal law requires manufacturers and distributors to submit ARCOS reports containing specific information about each transaction of opioids from manufacture, to distributor, to pharmacy. 21 C.F.R. § 1304.33.

The ARCOS data that distributors are required to submit is sensitive to pharmacies and distributors because it is confidential business information; and it is sensitive from the DEA's

perspective because it is crucial to law enforcement efforts. Extensive federal laws and regulations limit the circumstances in which the DEA may disclose ARCOS data. For instance, federal regulations permit the DEA to release information it obtains “to Federal, State, and local officials” only if they are engaged in “the enforcement of laws related to controlled substances” or “the institution and prosecution of cases before courts and licensing boards related to controlled substances.” 28 C.F.R. § 0.103(a)(1)-(2).

Federal law allows distributors of prescription opiates significant protections against FOIA requests for ARCOS data. FOIA exempts from public disclosure any confidential commercial information, the disclosure of which is likely to cause substantial competitive harm. *See* 5 U.S.C. § 552(b)(4); *Canadian Commercial Corp. v. Dep’t of Air Force*, 514 F.2d 37, 39 (D.C. Cir. 2008). Commercial information is also confidential if its disclosure would “impair the Government’s ability to obtain necessary information in the future.” *Canadian Commercial*, 514 F.2d at 39. If information falls within this exemption, it also falls within 18 U.S.C. § 1905, and its dissemination may result in fines and/or imprisonment. *See also CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1151-52 (D.C. Cir. 1987) (“the scope of the [Trade Secrets] Act is at least co-extensive with that of Exemption 4 of FOIA, and that, in the absence of a regulation effective to authorize disclosure, the Act prohibits [an agency] . . . from releasing any information . . . that falls within Exemption 4.”). And when the DEA receives a FOIA request, it is required to provide distributors pre-disclosure notice so that the distributors “may object to the disclosure of” the information. Exec. Order 12,600, 52 Fed. Reg. 23,781 (June 23, 1987). The DEA must then “give careful consideration” to any objection raised by the distributors. *Id.*

Exemption 7 of FOIA permits a federal agency to withhold records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement information could reasonably be expected to interfere with enforcement proceedings and criminal prosecutions. 5 U.S.C. § 552(b)(7). There are hundreds of ongoing enforcement proceedings and criminal prosecutions, and the fact that the data goes back 10 years does not mean that it is irrelevant to current investigations or future prosecutions.

Perhaps most important, the ARCOS data is not a record generated by the Counties that are, or may be, subject to state public records requests. It is a law-enforcement tool of the United States that it shares only with local law enforcement agencies to stem illicit drug-trafficking. Plaintiffs have gained the ARCOS data solely by virtue of the Court's discovery processes. The data does not transmogrify into a public record merely because it has been disclosed privately to the parties in this civil litigation.

The Court ordered disclosure of the ARCOS data to the States for law enforcement purposes, and to the Plaintiffs for this litigation alone, because it was the only way to ensure they had named the correct defendants. Plaintiffs have used this data to dismiss some defendants they had sued initially, and to add some defendants not initially sued. And while certain parties are preparing for trial, the Court is most heavily involved in global settlement negotiations which cannot be achieved absent the involvement of all proper parties. Allowing the ARCOS data to be disclosed to the Media pursuant to public records requests to the Counties would eviscerate the Court's Protective Order and contradict the bedrock principle that discovery is a private process, the sole purpose of which is to assist trial preparation and, in this case, global settlement discussions.

The March 2019 trial in this MDL will be open to the public, and the evidence presented will become a matter of public record. Until that time, all parties in this MDL are prohibited from disclosing the ARCOS data to the Media, or any other unauthorized user, absent a Court Order.⁸

III. Conclusion

The Court, having shown good cause for its Protective Order which prohibits the disclosure of ARCOS data obtained in the course of discovery in this MDL to unauthorized users, including the Media, sustains the objections to disclosure filed by the United States and Defendants.

IT IS SO ORDERED.

/s/ Dan A. Polster July 26, 2018
Dan Aaron Polster
United States District Judge

⁸Please note that this Opinion and Order applies to the many public records requests seeking ARCOS data from the parties in the MDL.